

RECEIVED
OPPT CBIC

201-15242

04 MAY -6 PM 12:15

Anh Nguyen

05/05/04 08:51 AM

To: NCIC HPV@EPA

cc:

Subject: Fw: Environmental Defense comments on Ethyl(3-methylphenyl)-Amino Acetonitrile (CAS# 63133-74-4)

----- Forwarded by Anh Nguyen/DC/USEPA/US on 05/05/2004 08:50 AM -----



rdenison@environmentaldefense.org

05/05/2004 08:48 AM

To: NCIC OPPT@EPA, ChemRTK HPV@EPA, Rtk Chem@EPA, Karen Boswell/DC/USEPA/US@EPA, Deyo@eastman.com

cc: luciarg@msn.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org

Subject: Environmental Defense comments on Ethyl(3-methylphenyl)-Amino Acetonitrile (CAS# 63133-74-4)

(Submitted via Internet 5/5/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, luciarg@msn.com and Deyo@eastman.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Ethyl(3-methylphenyl)-Amino Acetonitrile (CAS# 63133-74-4).

The test plan and robust summary for ethyl(3-methylphenyl)-amino acetonitrile (EMAA) was submitted by Eastman Chemical Company. The sponsor states that EMAA is used as a closed-system intermediate in the process used to synthesize color developer.

The test plan and robust summaries were informative and well-written, and we appreciate the detailed presentation of the industrial processes using EMAA. The justification for considering EMAA as a closed-system industrial intermediate was convincing; indeed, it could serve as a model for proposed closed-system intermediates submitted by other companies.

EMAA is used to synthesize N-ethyl-N-(3-methylphenyl)-1,2-ethanediamine (EMPE), which in turn is used to make CD-3 sulfonamide. CD-3 sulfonamide is an intermediate in the process used to make color developer CD-3. The sponsor indicates that regular testing of the color developer has never detected any residual EMAA. EMAA manufactured by the sponsor is made and entirely consumed at a single site, and is not transported off-site. The sponsor states that, to its knowledge, it is the sole manufacturer of EMAA. Unreacted EMAA, according to the sponsor, is sent to an on-site wastewater treatment facility or an on-site hazardous waste incinerator.

The sponsor proposes to conduct a combined reproductive/developmental toxicity study on EMAA. We agree with this proposal given that no studies are available on these endpoints. The sponsor points out that reproductive toxicity studies are not required for closed-system intermediates, but the proposed combined developmental/reproductive toxicity study will address reproductive toxicity concerns associated with potential exposure of workers. For the same reason, the sponsor may wish to add a repeat dose toxicity component to the combined reproductive/developmental toxicity study.

Other comments are as follows:

1. Available studies indicate that EMAA is moderately toxic to fish and aquatic invertebrates, and is highly toxic (1 mg/L) to algae. The sponsor proposes to address the water stability endpoint through technical discussion. We believe that, because EMAA is highly toxic to algae, a water stability study should be conducted.

2. The sponsor concludes that EMAA is not mutagenic, although one study produced an apparent increase in revertants in the Ames assay. However, this finding was not replicated, and we agree with the conclusion that EMAA

is not mutagenic.

3. Aqueous wastes containing EMAA are sent to an on-site wastewater treatment plant. However, no information was provided on the concentration of EMAA in the wastewater sent to the plant, nor were monitoring data provided for EMAA remaining after wastewater treatment. Likewise, no information was provided on concentrations of EMAA potentially released from reaction vessels, although modeling data were alluded to in the test plan. While not strictly required, monitoring data in air and water are needed to definitively conclude that EMAA is totally contained and consumed on-site.

4. The sponsor states that prudent worker safety practices are in place. It would be more informative if a brief summary of those practices along with data on workplace levels of EMAA could be provided.

Thank you for this opportunity to comment.

George Lucier, Ph.D.
Consulting Toxicologist, Environmental Defense

Richard Denison, Ph.D.
Senior Scientist, Environmental Defense